Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for venlafaxine, the scientific conclusions are as follows:

In view of available data on venlafaxine overdose from the literature, the risk of hypoglycaemia related to overdose is noted and should be added to the overdose symptoms for the awareness of health care professionals. The PRAC Lead MS concluded that the product information of products containing venlafaxine should be amended accordingly.

The CMDh agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for venlafaxine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing venlafaxine is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing venlafaxine are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~)

Summary of Product Characteristics

Section 4.9

In postmarketing experience, overdose with venlafaxine was reported predominantly in combination with alcohol and/or other medicinal products, including cases with fatal outcome. The most commonly reported events in overdose include tachycardia, changes in level of consciousness (ranging from somnolence to coma), mydriasis, convulsion, and vomiting. Other reported events include electrocardiographic changes (e.g., prolongation of QT interval, bundle branch block, QRS prolongation [see section 5.1]), ventricular tachycardia, bradycardia, hypotension, **hypoglycaemia,** vertigo, and deaths. Severe poisoning symptoms may occur in adults after intake of approximately 3 grams of venlafaxine.

Package Leaflet

Regarding the updates to the SmPC section 4.9, the package leaflet is not affected.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	December 2023 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	28 January 2024
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	28 March 2024